IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

ELIZABETH M. MCGATHEY,	)
	)
Plaintiff,	)
	) **CIVIL ACTION FILE**
v.	)
	) **NO._____**
ETHICON, INC., and	)
JOHNSON & JOHNSON, INC.,	)
	)
Defendants.	)
	)

COMPLAINT

COMES NOW, Plaintiff, Elizabeth M. McGathey herein and hereby files this Complaint, showing the Court as follows:

INTRODUCTION

1. This is a personal injury action brought for injuries caused to Plaintiff as result of having the Defendants' Products implanted in her, which caused her significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, and has suffered financial or economic loss.

2. It is anticipated that this case will be transferred as a tag-along action, In Re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation MDL 2327, which is now pending in the Southern District of West Virginia.

PARTIES

3. Plaintiff, Elizabeth M. McGathey ("Plaintiff") is a resident of the State of South Carolina.

4. Defendant, Johnson & Johnson, Inc. ("Johnson & Johnson") is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey.

5. Defendant Ethicon, Inc., ("Ethicon") a subsidiary of Johnson & Johnson, is a corporation existing under the laws of New Jersey, with its principal place of business at Route 22 West, Somerville, New Jersey.

6. Defendants, Johnson & Johnson, and Ethicon, will collectively be referred to as "Defendants."

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, based upon complete diversity jurisdiction in that Plaintiff is a citizen of a State different from the States where Defendants are incorporated and have their principal places of business, and because the amount in controversy exceeds seventy-five thousand dollars ($75,000.00).

8. Pursuant to 28 U.S.C. § 1391(a), venue is appropriate because a substantial part of the events leading to this claim arose in this district and because the Defendants are subject to personal jurisdiction by this Court.

FACTUAL BACKGROUND

9. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell and/or distribute the Gynecare Prolift, designed to treat pelvic organ prolapse. The Prolift was and is offered as an anterior, posterior or total repair system, and all references to the Prolift include all variations.

10. At all relevant times, Defendants were in the business of and did create, design,

manufacture, test, formulate, advertise, market, promote, sell and/or distribute the Gynecare TVT, designed to treat urinary incontinence. The TVT was and is offered in multiple variations including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include all variations.

11. The Prolift and the TVT will collectively be referred to as "Products."

12. The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as safer and more effective as compared to the traditional products and procedures for treatment.

13. Defendants knew or should have known, that the Products had been insufficiently tested; that they were defectively created, designed, manufactured, tested and formulated, lacked adequate warnings, and were negligently and recklessly advertised, marketed, promoted and sold.

14. The Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

15. On October 20, 2008, the FDA issued a public health notification alerting the medical community that transvaginal placement of mesh device systems, including the Prolift, could lead to potentially serious complications including erosion of the material, infection, pain, urinary complications, and recurrence of prolapse or incontinence.

16. In a study published in August 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion rate with the Prolift, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs."

Numerous studies published in influential medical journals have reached similar conclusions.

17. Upon information and belief, Defendants misrepresented the risks inherent in the use of the Products in their applications for approval to the FDA and to other governmental persons and/or agencies.

18. Defendants have consistently underreported and withheld information about the propensity of Defendants' Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

19. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

20. Defendants failed to design and establish a safe, effective procedure for removal of the Products; therefore, in the event of a failure, injury or complaint it is impossible to easily and safely remove the Products.

21. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar conditions have existed at all times relevant.

22. The Products were at all times utilized and implanted in a manner foreseeable to the Defendants.

23. Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Products, and thus increase the sales of the Products.

24. The injuries, conditions and complications suffered due to Defendants' Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve

damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and often additional intensive medical treatment, including but not limited to operations to locate and remove mesh, attempts to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications.

25. Despite Defendants' knowledge of these injuries, conditions, and complications caused by their Products, the Defendants have and continue to manufacture, market, and sell the Products, while continuing to fail to adequately warn, label, instruct and disseminate information with regard to the Defendants' Products, both prior to and after the marketing and sale of the Products.

26. On or about October 20, 2008, Plaintiff was implanted with the Products by Dr. Rice at St. Francis Hospital located in Greenville, South Carolina.

27. The Products were implanted in Plaintiff to treat her pelvic organ prolapse and urinary incontinence, the use for which Products were designed, marketed and sold.

28. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

29. Plaintiff incorporates by reference paragraphs 1–28 of this Complaint as if fully set forth herein.

30. The negligence and carelessness of the Defendants, jointly, severally, acting in concert and via their agents, servants, and/or employees, included but was not limited to the

following acts and/or omissions:

a. Designing, manufacturing, supplying, and distributing the Products in a defective condition when they knew or should have known of said defects;

b. Failing to act reasonably to identify, eliminate, or reduce the risks of hazards associated with the intended and foreseeable uses of the Products;

c. Failing to utilize existing technology or to apply established engineering, scientific and medical principles to eliminate or reduce the risks and hazards associated with the intended and foreseeable uses of the Products;

d. Designing, manufacturing, supplying, and distributing Products, which were unreasonably dangerous, unsafe, and defective with regard to all of their intended and foreseeable purposes and uses;

e. Designing, manufacturing, supplying and distributing the Products without proper safeguards, safety devices, safety appliances, and safety equipment;

f. Designing, manufacturing, supplying, and distributing the Products, which were improper for the purpose(s) for which Defendants knew they would be used;

g. Designing, manufacturing, supplying and distributing the Products without adequate warnings;

h. Negligently designing, manufacturing, supplying and distributing the Products;

i. Failing to advise Plaintiff's physician of the dangers associated with the use of the Products;

j. Failing to advise Plaintiff of the dangers associated with the use of the Products, which deprived her of an opportunity to make an informed choice with regard to the surgery;

k. Failing to comply with standards, specifications and regulations in the industry;

l. Failing to comply with federal and state statutes and regulations;

m. Failing to adequately test the Products; and

n. Failing to conduct adequate post-marketing surveillance of the Products.

31. As a direct and proximate result of the negligence and carelessness of Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT II: STRICT LIABILITY

32. Plaintiff incorporates by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

33. Defendants, by and through their agents, servants, employees and/or ostensible agents are strictly liable to Plaintiff because at all times herein mentioned the Defendants manufactured, compounded, distributed, recommended, merchandized, advertised, promoted, sold, purchased, prescribed and otherwise facilitated the Products as hereinabove described in violation of applicable statutes, regulations and appropriate standards of care.

34. The Products were expected to and did reach the usual consumers, handlers and persons coming into contact with such Products, including Plaintiff and her medical providers, without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by Defendants.

35. At those times, the Products were in an unsafe, defective and inherently dangerous condition, which was hazardous to users, including Plaintiff, and the public at large.

36. Defendants, while regularly engaged in the business activities aforementioned, did design, develop, manufacture, produce, test, sell, market, and/or distribute the Products which were surgically implanted in Plaintiff.

37. At all times herein mentioned, the Products were in an unsafe and defective condition and Defendants, individually, jointly, and severally, knew or had reason to know that the Products were defective and unsafe in violation of applicable statutes, regulations, and appropriate standards of care.

38. The Products were, and still are, inherently dangerous.

39. At the time of Plaintiff's surgeries, the Products were being used for the purposes and in the manner Defendants intended.

40. As a direct and proximate result of the defective condition of the products manufactured and supplied by Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT III: BREACH OF IMPLIED WARRANTY

41. Plaintiff incorporates by reference paragraphs 1–40 of this Complaint as if fully set forth herein.

42. In manufacturing, marketing, distributing and selling the Products, Defendants owed a duty to users, including Plaintiff, to provide products, which were fit for the ordinary purpose for which they were used, and to ensure that the products conformed to the promises and affirmations made to the ultimate consumer, in this case, Plaintiff.

43. Defendants knew or should have known that the general public and Plaintiff in particular relied on them to provide products which were fit for their ordinary or intended use and which would conform to the promises and affirmations concerning them.

44. Defendants knew or should have known that the general public and Plaintiff in particular relied on them to provide products which were fit for their ordinary or intended use and which would conform to the promises and affirmations concerning them.

45. Defendants knew or should have known that the general public and Plaintiff in particular relied on them to provide products which were fit for their ordinary or intended use and

which would conform to the promises and affirmations concerning them.

46. Defendants, as more specifically set forth above, breached their duties and implied warranty of merchantability.

47. As a direct and proximate result of Defendants' breaches of their duties and implied warranties of merchantability, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT IV: BREACH OF EXPRESS WARRANTY

48. Plaintiff incorporates by reference paragraphs 1–47 of this Complaint as if fully set forth herein.

49. Defendants expressly warranted that the Products were safe and suitable for use as reinforcement for human tissue in certain types of surgery associated with pelvic organ prolapse and urinary incontinence.

50. The Products failed to conform to the express warranties of Defendants.

51. As a direct and proximate result of Defendants' breaches of their duties and implied warranties of merchantability, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT V: FRAUDULENT MISREPRESENTATION

52. Plaintiff incorporates by reference paragraphs 1-51 of this Complaint as if fully set

forth herein.

53. At all relevant times, Defendants jointly, severally, acting in concert, with or through others, their agents, servants, and/or employees made false and fraudulent representations to the medical community and eventual recipients of the Products, including by not limited to representations that the Products and their components had been tested and found to be safe and effective products for surgery.

54. Defendants knew or should have known these misrepresentations to be false. Nevertheless, Defendants willfully, wantonly, and recklessly disregarded the falsity of their statements; made representations fraudulently and deceitfully with the intent to induce women to seek surgical treatment involving the Products, and did in fact induce them; and induced the medical community to recommend, dispense, purchase, and provide surgical treatment to these women. All of Defendants' above acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety and welfare of the system's intended recipients, including the Plaintiff.

55. At the time Defendants made their misrepresentations, recipients of the Products, including Plaintiff, could not by the exercise of their own reasonable care discover the falsity of Defendants' misrepresentations and, instead, reasonably believed them to be true.

56. Defendants sought and in fact did obtain FDA approval of the Products in their defective form, based on Defendants' fraudulent misrepresentations, and Defendants inserted the system into the stream of commerce, causing harmful effects to recipients thereof. Defendants knew or should have known that the Products had been insufficiently tested, lacked adequate warnings, and would lead to serious injury amongst its recipients. Defendants thereby breached their

duty to Plaintiff, other recipients of the system and the medical community.

57. As a direct and proximate result of Defendants' fraudulent conduct and misrepresentations, made jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone corrective surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

WHEREFORE, Plaintiff demands trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Date: April 30, 2012

Respectfully submitted,

s/ Thomas M. Creech Jr.
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